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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,304

09/24/2003

Bronislava Gedulin

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8486

7590

06/14/2006

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EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,304	Applicant(s) GEDULIN ET AL.	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0105 and 0904</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of species of an amylin analog in the reply filed on 04/21/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Readable claims 1-16 and 18-20 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog 25,28,29 Pro-h-amylin, the specification does not enable any person in the art for preparing a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs. Applicant has reasonably demonstrated on pages 24-30 (examples 1-3, especially example 2) of the specification a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs. For example, Reid et al. teach (US 6869926, see.e.g. abstract) that an amylin analog treats cartilage disorders by stimulating chondrocyte proliferation. Thus, the art is silent regarding the efficacy of applicant's method for treating pancreatitis and/or relieving the

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pain caused by pancreatitis comprising administering any and/or all amylin analogs.

Therefore, applicant's claimed method is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on pages 24-30 (examples 1-3, especially example 2) of the specification a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs. Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 5,677,279) in further view Braganza et al. (US 5,196,402) and Jorgensen et al. (US 4,370,317).

Applicant claims a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject (i.e. human) comprising administering to

said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin, an analgesic and a pancreatic enzyme.

Young teaches (see, e.g. see abstract, claims and claims 18-19) a method of relieving the pain in a mammalian subject comprising administering to said subject an effective amount of the same amylin analog as the claimed invention amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to treat pain. Young does not teach that the mammalian subject's pain is caused by pancreatitis and the claimed pancreatic enzyme.

Braganza et al. beneficially teach (see, e.g. column 1 lines 10-15) that pancreatitis is a very painful condition and/or disorder.

Jorgensene et al. beneficially teach (see, e.g. column 8 lines 36-41) that pancreatin treats pancreatitis (please note that pancreatin is defined as an extract from the pancreas of animals that contains pancreatic enzymes).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful disorder of pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and an analgesic treats painful disorders and Braganza teaches that pancreatitis is a painful disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating pain, it would intrinsically treat the painful disorder of pancreatitis within a mammalian

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subject when treating the pain. Moreover, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to include the teaching of Young which states a pancreatic enzyme is well known in the art for treating pancreatitis because the above combined teachings would create an improve method of administering of treating the painful disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER